REMARKS

Entry of this preliminary amendment is respectfully requested and is believed appropriate under 37 C.F.R §1.115

Upon entry of this paper, claims 1, 25, 26, 27, 44, 45, and 50 have been amended, no claims have been canceled, and no claims have been added as new claims, thus claims 1-27 and 44-52 are presently pending in this application. No new matter has been added.

Additional Remarks

Applicants wish to make some additional remarks based on rejections in the original application from the most recent substantive Office Action, in view of the amendments made by this Preliminary Amendment.

Claim Rejections under 35 U.S.C. §102

Claims 1, 3, 4, 6-20, 24-27, and 44

Claims 1, 3, 4, 6-20, 24-27, and 44 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,336,178 to Kaplan (Kaplan '178).

Applicants' preliminary amendments further clarify that the wall of the radially expandable fluid delivery device is ". . . formed of a microstructure of nodes interconnected by fibrils . . ." and that the ". . . wall of the member includes at least one microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the micro-channels, substantially controlling the permeation of fluid through the wall." *See* independent claims 1, 26, and 44, *see also* similar language in claims 25 and 27.

Applicants further distinguish the claimed invention from Kaplan '178 according to the following remarks.

Claims 1, 3, 4, 6-20, 24-27, and 44 Are Novel In View Of Kaplan '178 Because Kaplan '178 Does Not Contain Micro-Channels In The Wall Of The Expandable Body Through Which Fluid Can Permeate

Applicants respectfully submit that the micro-porous structure of the present invention is formed of micro-channels created by the micro-structure of the walls of the expandable member. This is in contrast to Kaplan '178, which contains holes along delivery conduits placed outside of the wall of the expandable member. Kaplan '178 does not teach a fluid expanding the expandable member and permeating through the walls of the member to an area outside of the member. Instead, the actual wall of Kaplan '178 serves only as a base for mounting a series of conduits.

Claims 1-4, 6-10, 13-20, 24-27, and 44-49

Claims 1-4, 6-10, 13-20, 24-27, and 44-49 were also rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5, 843, 069 to Butler (Butler '069).

Claims 1-4, 6-10, 13-20, 24-27, and 44-49 Are Novel With Respect To Butler '069 Because There Is No Disclosure In Butler '069 Of A Fluid Permeable Wall Of Micro-Channels

Applicants wish to further clarify the present invention as claimed in claims 1, 25, 26, 27, 44, and 45, and its novelty with respect to Butler '069. Claims 1, 25, 26, 27, 44, and 45 claim that the wall of the member includes at least one microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the micro-channels, substantially controlling the permeation of fluid through the wall. *See* claims 1, 25, 26, 27, 44, and 45.

There is no disclosure in Butler '069 of a device wherein walls are formed of a micropourous structure creating micro-channels through which fluid permeation can occur in a controlled manner.

Claim Rejections under 35 U.S.C. §103

Claims 5, 21-23, and 50-52

Claims 5, 21-23, and 50-52 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Butler '069. As discuss above, the addition of Butler '069 does not result in a teaching of all claimed elements in the amended claims. Absent a teaching of all of the claimed elements, there can be no obviousness rejection.

Additional Reference and Remarks

Applicants are submitting an Information Disclosure Statement herewith, in which US Patent No. 6,120,477 to Campbell (Campbell '477) is provided. Applicants wish to provide some preliminary remarks concerning Campbell '477.

Summary of Campbell '477

Campbell '477 is directed to balloon catheters having the strength and maximum inflated diameter characteristics of an angioplasty balloon and having the recovery characteristics during deflation of an elastic embolectomy balloon. The balloon catheter can be made in very small sizes and has a lubricious and chemically inert outer surface. The balloon catheter is easy to navigate through tortuous passageways, is capable of rapid inflation and deflation, and has high burst strengths. Balloon covers having these same characteristics are also described for use with conventional embolectomy balloons or angioplasty balloons.

The Present Claimed Invention, As Amended, Is Allowable Over Campbell '477 Because Campbell '477 Does Not Disclose All Claimed Elements Of The Present Invention

Campbell '477 does not disclose a ". . . radially expandable fluid delivery device comprising: a member . . . having a . . . wall having a thickness extending between an inner and an outer surface, the wall being formed of a microstructure of nodes interconnected by fibrils, . . . wherein the wall . . . includes at least one microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the micro-channels, substantially controlling the permeation of fluid through the wall." *See* Claim 1, *see generally*, Claims 25, 26, 27, 44, 45, and 50.

Campbell '477 alludes to balloons eluting fluids when it states, "[b]alloons of the present invention can also be constructed to elute fluids at pressures exceeding the balloon inflation pressure." *See* column 4, lines 26-28. However, Applicants can find no further reference in Campbell '477 regarding such a balloon structure. Furthermore, the statement provided in Campbell '477 does not describe in any manner the structure of such a balloon, or the method by which a liquid might elute through the balloon. As such, the feature alluded to in Campbell '477 is considered by Applicants to refer to the conventional perforation of balloons to create larger openings through which fluid can elute, not the novel formation of micro-channels within the microstructure of the wall as claimed in the present invention.

There is no discussion in Campbell '477 of a microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the micro-channels in a controlled manner. As such, Applicants believe the claimed invention to be both novel and non-obvious with respect to Campbell '477.

CONCLUSION

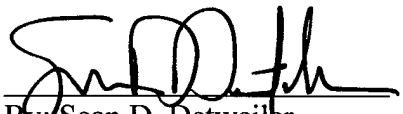
In light of the above comments, applicants respectfully submit that the claims of the present invention, as amended, are not anticipated by, and are non-obvious in view of, the cited references. Therefore, Applicants respectfully request allowance of the application as amended.

Attached hereto is a marked-up version of any changes made to the Specification and/or Claims by the current Amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Should there be any questions regarding the proposed amendments to the application, a telephone interview is respectfully requested to resolve such issues.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claims 1, 25, 26, 27, 44, 45, and 50 as follows:

1. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the member includes at least one microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the ~~wall, spaces~~ micro-channels, ~~between the nodes~~ substantially controlling the permeation of fluid through the wall.

25. (Amended) An expandable drug delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force to the lumen, a least a portion of the wall having nodes oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface to the outer surface of the wall, the micro-channels being sized to permit fluid including a therapeutic agent to expand the drug delivery device and permeate from the inner surface to the outer surface of the wall.

26. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force,

wherein the wall of the member includes a first microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the wall, and a second microporous portion of micro-channels formed by the microstructure spaced apart from the first microporous portion and having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the wall.

27. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible fluoropolymer material, the tubular member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall being formed of a microstructure of nodes interconnected by fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration upon application of an expansion force from a fluid, the wall including a microporous portion having nodes oriented such that spaces between the nodes form micro-channels extending from the inner surface to the outer surface of the wall, the micro-channels being sized to permit ~~a~~ the fluid to permeate from the inner surface to the outer surface of the wall,

wherein the size of the micro-channels varies circumferentially about the tubular member to provide regions of greater porosity within the microporous portion.

44. (Amended) A medical treatment device comprising:

a catheter having an elongated hollow tube defining an inflation lumen extending from a proximal end to a distal end, and

a balloon constructed of a biocompatible fluoropolymer material and attached to the distal end of the tube, the balloon having a wall having a thickness extending between

an inner and an outer surface and a lumen in fluid communication with the inflation lumen of the catheter, the wall being formed of a microstructure of nodes interconnected by fibrils, the balloon being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the balloon includes at least one microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the medical treatment device and permeate through the wall, substantially all of the nodes within the microporous portion being oriented substantially perpendicular to the longitudinal axis of the balloon.

45. (Amended) A radially expandable fluid delivery device having a longitudinal axis and a wall transverse to the longitudinal axis, the fluid delivery device comprising:

a first layer of biocompatible material being formed of a microstructure of nodes interconnected by fibrils, and

a second layer of biocompatible material being formed of a microstructure of nodes interconnected by fibrils, the second layer overlying the first layer, the wall of the fluid delivery device extending between an inner surface of the first layer and an outer surface of the second layer, the fluid delivery device being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the fluid delivery device is formed of at least one microporous portion having a porosity sufficient for a fluid to permeate through the wall, substantially all of the nodes within the microporous portion being oriented such that spaces between the nodes form generally aligned micro-channels oriented and extending from the inner surface of the first layer to the outer surface of the second layer, the micro-channels being sized to permit fluid to expand the fluid delivery device and permeate from the inner surface of the first layer to the outer surface of the second layer.

50. (Amended) A radially expandable fluid delivery device comprising:

a member constructed of a biocompatible material, the member having a longitudinal axis and a wall being formed of a microstructure of nodes interconnected by

fibrils, the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration,

wherein the wall of the member includes at least one microporous portion of micro-channels formed by the microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through the wall, the microporous portion having a hydraulic conductivity less than 1000 (cm^4/ (dyne* s)* 10^{12}).